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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,589	03/21/2001	Stephen A. Goff	S-20359D	1510
7590	04/28/2004			
EXAMINER				WOITACH, JOSEPH T
				ART UNIT 1632
				PAPER NUMBER
				DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,589	GOFF ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 February 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 26,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 26, 39 and 40 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

This application is a continuation of Application 09/625,904, filed July 26, 200, now abandoned, which is a continuation of Application 9/234,190, filed 1/20/1999, which is a division of Application 9/010,050, filed 1/21, 1998, now patent 5,880,333, which is a continuation of application 8/398,037, filed 3/3/1995, abandoned.

Applicants' amendment filed February 11, 2004, has been received and entered. The specification has been entered. Claims 1-25, 27-38 and 41 have been canceled. Claims 26 and 40 have been amended. Claims 26, 39 and 40 are pending and currently under examination.

Information Disclosure Statement

As noted in the previous office action, the information disclosure statement filed March 21, 2001, attachment to paper number 2, indicates that the listed references are provided in parent application 09/625,904. Upon review of the file of application 09/625,904 Examiner indicated the references which were provided in the parent application, however Tomlin (AA3) reference was not provided.

The Tomlin (AA3) reference was not provided with the instant amendment for review.

Abstract

The substitute abstract submitted February 11, 2004 is acceptable.

The deletion of the legal phraseology such as "means" and "said" has obviated the basis of the objection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 41 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn.

Cancellation of the claim has rendered the rejection moot.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn.

The amendment to the claim to encompass a plant cell has obviated the basis of the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26 and 39 rejected under 35 U.S.C. 103(a) as being unpatentable over Schena *et al.* in view of Koelle *et al.* and Christopherson *et al.* is withdrawn.

Claims 26 and 39 rejected under 35 U.S.C. 103(a) as being unpatentable over Schena *et al.* in view Evans *et al.* (WO94/01558) is withdrawn.

The amendment of claim 26 to include the limitations of claim 30, which was not subject to the instant rejection and free of the art of record, has differentiated the claimed invention from that made obvious by Koelle *et al.* and Christopherson *et al.* and Schena *et al.* in view Evans *et al.*

Claim 35 rejected under 35 U.S.C. 103(a) as being unpatentable over Schena *et al.* in view Evans *et al.* as applied to claims 26, 33, 34 and 37-39 above, and further in view of Christopherson *et al.* is withdrawn.

Cancellation of claim 35 has rendered the basis of the rejection moot.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26, 39 and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-19 of U.S. Patent No. 5,880,333. Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass the same combination of claimed elements. In particular each claim set comprises the same elements for (a) and (c), and with respect to (b) set forth an 'Ecdysone receptor' that comprises the 'heterologous transactivation domain from the C1 regulatory gene of maize' (compare claim 26 with claim 17 and also with claim 18 combined with dependent claim 19). Claim 17 does not specifically recite that the Ecdysone receptor has a ligand binding domain and a DNA binding domain as in claim 26, however these are known domains present in the normal receptor. Moreover, without these domains the claimed Ecdysone receptor would be non-functional and without any enabled use as taught in the instant specification. Similarly, claim 18 does not set forth a transactivation domain but does recite a specific DNA binding domain. Again as discussed for claim 17, the Ecdysone receptor

comprises three domains and without each of these domains the claimed Ecdysone receptor would be non-functional and without any enabled use as taught in the instant specification.

There are no claims in '333 that specifically recite that the vector is comprise in an expression cassette or in a plant cell, however these are obvious limitations required for the use of the claimed expression cassette and made obvious by the teachings of the specification and by the claimed methods (for example the combination of claims 1, 5, 6 and 10).

Claims 26, 39 and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, 11, 12, 16, 26, 27, 29 and 30 of U.S. Patent No. 6,147,282. Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass the same combination of claimed elements. It is noted that the claims of '282 are method claims not product claims, however the method requires the use of instantly claimed expression cassette for practicing the method. In particular the method steps recite that an expression cassette encoding a receptor (claim 1) wherein the receptor is the Ecdysone receptor (claim 8) that has a DNA binding domain (claims 11, 12, 26 and 30 for example) and that it has a transactivation domain, specifically the 'C1 regulatory gene of maize' (claims 16 and 29). It is noted that none of the method claims specifically set forth the 5' and 3' regions as set forth in (a) and (c) of claim 26, however these are obvious and required elements for the expression of the receptor in the context of the claimed methods as taught by the specification and generally known in the art for expression vectors.

Conclusion

No claim is allowed.

The claims are free from the art of record in view of the prior art to teach or suggest the claimed combination of C1 regulatory gene of maize with other receptor gene domains under the control of a plant promoter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

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